

Translation

PATENT COOPERATION TREATY

PCT/JP2003/010846



# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PH-1839-PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2003/010846	International filing date (day/month/year) 27 August 2003 (27.08.2003)	Priority date (day/month/year) 30 August 2002 (30.08.2002)
International Patent Classification (IPC) or national classification and IPC C12Q 1/68, C12N 15/31		
Applicant NICHIREI CORPORATION		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows: <div style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</div> b. <input checked="" type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) Disc 1 _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <div style="margin-left: 40px;"><input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input checked="" type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input checked="" type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application</div>

Date of submission of the demand 20 January 2004 (20.01.2004)	Date of completion of this report 05 March 2004 (05.03.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
  - ☒ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

The inventions of claims 1-15 are inventions concerning primers that contain bases specific to *Vibrio vulnificus* in the gene that encodes the  $\beta$  subunit of DNA gyrase.

The inventions of documents 16-36 are inventions that concern primers that contain bases specific to *Vibrio vulnificus* in the gene that encodes the RNA polymerase  $\sigma$  factor.

The inventions of claims 37-50 are inventions that concern primers that contain bases specific to *Vibrio vulnificus* in the gene that encodes RecA.

The common technical feature of the inventions of the inventions of claims 1-15, 16-36, and 37-50 is the *Vibrio vulnificus* family of bacteria, but because this family of bacteria is publicly known, the common technical feature of the inventions of claims 1-15, 16-36 and 37-50 is not novel.

As a result, there is no matter that is common to all of the claims.

Because no other common matter is present that can be considered a special technical feature in the sense of PCT Rule 13.2 (2), no technical relationship in the sense of PCT Rule 13 can be found in these different groups of inventions.

As a result, the inventions of claims 1-15, 16-36, and 37-50 clearly do not satisfy the requirement for unity of invention.

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☒ all parts.
- ☐ the parts relating to claims Nos. \_\_\_\_\_

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims	1-50	YES
	Claims		NO
Inventive step (IS)	Claims	1-50	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-50	YES
	Claims		NO

**2. Citations and explanations (Rule 70.7)**

Document 1: JP 09-252783 A (Nippon Suisan Kaisha, Ltd.) September 30, 1997  
 Document 2: Appl. Environ. Microbiol., 1998, Vol. 64, No. 2, pages 681-7  
 Document 3: JP 07-213299 A (Marine Biotechnology Institute Co., Ltd.) August 15, 1995  
 Document 4: JP 2001-245677 A (SRL, Inc.) September 11, 2001  
 Document 5: Japanese Society of Food Microbiology Gakujutsu Sokai Koen Yoshishu, 2001, 22nd, Page 36  
 Document 6: JP 08-256798 A (Marine Biotechnology Institute Co., Ltd.) October 8, 1996  
 Document 7: Infect. Immun., 2000, Vol. 68, No. 12, pages 7180-5

**•Claims 1-50**

Documents 1-7 cited in the international search report do not describe the inventions of claims 1-50, and therefore these inventions are novel and involve an inventive step.

Documents 1-7 do not describe a gene that encodes the  $\beta$  subunit of DNA gyrase, the gene that encodes the RNA polymerase  $\sigma 70$  factor, and the gene that encodes RecA from *Vibrio vulnificus*, and persons skilled in the art cannot easily conceive of these matters.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
JP 2003-047474 A [E, X]	18.02.2003	03.08.2001	

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

## Supplemental Box Relating to Sequence Listing

## Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:
  - a. type of material
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material
    - ☐ in written format
    - ☒ in computer readable form
  - c. time of filing/furnishing
    - ☐ contained in the international application as filed
    - ☒ filed together with the international application in computer readable form
    - ☐ furnished subsequently to this Authority for the purpose of search and/or examination
    - ☐ received by this Authority as an amendment\* on \_\_\_\_\_
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

*\* If item 4 in Box No. 1 applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*